IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY
This Document Relates To: All Actions	

PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE DEFENDANTS FROM INTRODUCING EVIDENCE OF EVENTS OCCURING ON OR AFTER MAY 27, 2014

Pursuant to the Court's prior rulings and Federal Rule of Evidence 403, the plaintiffs respectfully move this Court to preclude the defendants from offering argument or evidence at trial about facts purportedly occurring since May 27, 2014 as a basis to dispute antitrust liability in this case. Facts occurring from May 27, 2014 through the present should be off the table for all parties at trial. Plaintiffs raise this now because bells pealed in opening statements cannot be un-rung.

In its summary judgment opinion, this Court recognized that there is evidence that Teva slowed its efforts to secure regulatory approval once AstraZeneca paid it off. To the extent that Defendants may intend to argue at trial that, for example, the fact that the FDA has not approved a generic since May 27, 2014 somehow supersedes the impact of their earlier anticompetitive acts, that argument lacks foundation. To substantiate such an argument, Defendants would have to adduce proof that (i) the Ranbaxy and Teva's current efforts to have the FDA approve their generic products are uncontaminated by the delayed entry date built into their agreements, and (ii) the Defendants recent, voluntary, decisions regarding FDA generic entry are unaffected by an

interest in molding evidence for this case. Defendants have made no effort to create this necessary record.

To make things worse, Defendants successfully rebuffed plaintiffs' efforts to take discovery about post-May 27, 2014 events to test this foundationless assertion. Plaintiffs asked Ranbaxy and Teva to produce documents showing a complete picture of the regulatory status of their ANDAs post May 27, 2014. Both refused to make a fulsome production. Plaintiffs moved to compel this information from Ranbaxy. The defendants successfully opposed. So plaintiffs do not know what *did* happen after May 27, 2014, let alone *why*. At best, plaintiffs know from media reports that Ranbaxy and five of its senior executives recently parted ways, including Venkatachalam Krishnan who had been responsible for getting Ranbaxy's generic Nexium to market. This trial by ambush is entirely inconsistent with the Federal Rules of Civil Procedure and threatens the integrity of the trial set to begin Monday.

Because such evidence would both lack foundation and be unduly prejudicial, this Court should exclude at trial argument or evidence about facts occurring from May 27, 2014 through the present.[1]

I. BACKGROUND

A. Plaintiffs tried to obtain post-May 27, 2014 discovery, but defendants refused to comply.

Plaintiffs propounded three sets of document requests to defendants Ranbaxy and Teva during the discovery period in this case.[2]

---

[1] Plaintiffs do not seek to exclude evidence that was *produced or received* after May 27, 2014 that refers to facts or events that occurred before May 27, 2014.

[2] Plaintiffs served on defendants Plaintiffs' First Request for Production of Documents to All Defendants, dated November 21, 2012; Plaintiffs' Second Request for Production of Documents to All Defendants, dated May 1, 2013; and Plaintiffs' Third Request for Production of Documents to All Defendants, dated July 12, 2013 (collectively, "plaintiffs' RFPs"). Fact discovery closed on July 1, 2013.

On May 21, 2014, plaintiffs asked Ranbaxy and Teva to produce additional documents created *after* the date of its last production responsive to specific requests that plaintiffs had propounded during the discovery period. Plaintiffs did not request that Ranbaxy or Teva search for supplemental documents pertaining to *every* previous request for production.

In response, Ranbaxy wholesale objected to the entirety of plaintiffs' requests for supplementation and merely identified some types of requested documents which it purports it does not have. Despite plaintiffs narrowing their requests to only *four* of plaintiffs' previous document requests – documents and communications between Ranbaxy and FDA concerning its esomeprazole ANDA; documents and communications concerning Ranbaxy's performance under an FDA consent decree and import ban; and documents and communications between Ranbaxy and AstraZeneca concerning Ranbaxy's performance under their API Supply and Tolling agreements – Ranbaxy continued to refuse to supplement its production of these requested documents.

Teva would only agree to make a self-serving supplemental production of its ANDA file (just the official correspondence to and from FDA), and would not agree to produce any internal emails or memos about those efforts or the timeframe in which they would be completed.[3] Teva then later refused to make any supplemental production unless plaintiffs would agree to a *simultaneous* production of Nexium purchase data and Teva refused to produce documents relating to Ranbaxy's possible relinquishment, waiver, retention or forfeiture of the 180-day exclusivity for esomeprazole.

[3] *Id.* Teva made a limited supplemental production from its ANDA file on June 4, 2014, and September 9, 2014, totaling approximately 6 documents. Plaintiffs additionally sought internal correspondence and correspondence with FDA or any other entity concerning Teva's ANDA.

On August 19, 2014, plaintiffs moved this Court to compel a limited supplemental production of documents by Ranbaxy.[4] This Court denied the discovery request on September 5, 2014.[5]

B. Teva has attempted to backdoor post- May 2014 evidence into this case.

Notwithstanding defendants Ranbaxy's and Teva's utter refusal to produce even a scintilla of the narrow categories of evidence plaintiffs have requested solely for the post-May 2014 time period, Teva disclosed a new, never previously disclosed expert, Gordon Johnston, on August 25, 2014. [6] On October 9, 2014, Teva served a supplemental report of Mr. Johnston which not only references facts from *post-May 27, 2014*, but also uses that purported evidence to show what would not have happened in the but-for world. He opines:

> For example, the fact that Teva does not have even tentative FDA approval as of today [Oct. 9, 2014] even though Teva has had a license from AstraZeneca to enter the market since May 2014 directly contradicts Dr. Blume's and Mr. Morrison's opinions that the FDA tends to permit pharmaceutical companies to enter the market as soon as they are licensed to do so.[7]

II. ARGUMENT

It is apparent that defendants may well attempt at trial to backdoor facts occurring on May 27, 2014 or after, which have been untested by plaintiffs as a result of the defendants' refusal to produce the necessary discovery, to support a foundationless argument that what has

---

[4] *See* ECF No. 971.

[5] *See* ECF No. 978.

[6] Pursuant to the amended Case Management Order in this case, the deadline for completion of merits expert discovery was December 4, 2013.

[7] *See* Supplemental Expert Report of Gordon Johnston dated Oct. 9, 2014 at 2.

actually happened since May 27, 2014 is predictive of what would have happened in the absence of the Defendants' earlier anticompetitive conduct.

A. Given the record, any argument that events occurring on May 27, 2014 or after show what would have happened in the absence of Defendants' anticompetitive scheme lacks foundation.

Defendants have not produced any evidence to establish a link between post- May 2014 events and what would have occurred after May 27, 2014 in the absence of Defendants' earlier anticompetitive conduct.[8] Yet, Defendants may try to argue at trial that, for example, the fact that the FDA has not approved a generic since May 27, 2014 somehow immunizes their earlier anticompetitive acts.

The Court has already rejected Teva's argument that the fact that Teva does not have FDA approval precludes a finding that it could not have obtained final approval before May 27, 2014.[9] In reaching this conclusion, the Court held that a jury could conclude based on Plaintiffs' evidence that Teva had "deliberately stalled that opportunity as a result of its settlement with AstraZeneca."[10] As it explained, the "timing and content of the change in tone of Teva's internal communications and documents, as well as Teva's agreement to set May 27, 2014 as a new proposed launch date, provide ample grounds for a reasonable juror to conclude that Teva was well on its way to obtaining tentative approval as of early 2008, and that it has since slowed its progress in response to the terms of its settlement with AstraZeneca." [11]

---

[8] *See In re Nexium*, 2014 WL 4370333 at *48.

[9] *In re Nexium (Esomeprazole) Antitrust Litig.*, ___ F. Supp. 2d ___, 2014 WL 4370333 at *48 (D. Mass. Sept. 4, 2014).

[10] *Id.*; *see also id.* at *31 (recognizing that "Ranbaxy curtailed its activities in light of the entry date that it had negotiated with AstraZeneca").

[11] *Id.* at *50.

The inferences that Defendants seek to draw from the post-2014 facts are not supported by evidence establishing each link in the "logical chain." Their argument amounts to nothing more than the naked assertion that Teva would "not have received faster approval had it started trying on an earlier date," an argument that the Court rejected at summary judgment.[12] Without evidence that the post -2014 facts are relevant to establishing what would have happened in the absence of Teva's delay, their admission would amount to nothing more than "layer[ing] hypothetical scenario upon hypothetical scenario."[13]

B. Introducing argument or evidence about facts occurring on or after May 27, 2014 is unduly prejudicial.

Permitting Defendants to refer, at trial, to facts favorable to them about what has happened since May 27, 2014[14] after they refused to provide Plaintiffs with the discovery necessary to test the Defendants' assertions about what those facts mean is unduly prejudicial to Plaintiffs.

Ranbaxy and Teva refused to produce complete discovery about the status of their ANDAs after May 27, 2014. And the Court denied Plaintiffs motion to compel such information. Teva has selectively produced a small amount of self-serving documents, including some post May 27, 2014 communications with the FDA, but Teva has not produced, for example, Teva's internal communications about to show whether issues raised by the FDA were a difficult to resolve or could be easily addressed, whether Teva chose to address those issues as quickly as possible or more slowly as a result of potential consequences in this litigation, etc.

---

[12] *Id.*

[13] *In re Nexium,* 2014 WL 4370333 at *35.

[14] One could argue that Defendants' conduct beginning as early as when the first of these antitrust cases was filed in August 2012 may well be tainted by a desire to mold the evidence. Plaintiffs do not go so far here as to ask that argument or evidence from August 2012 through the present should be precluded.

Defendants did produce a report by a new expert that focuses on post-May 17, 2014 facts. Mr. Johnston cites to facts about what has happened with the FDA's review of Teva's ANDA since May 27, 2014 as reasons that Teva's ANDA could not have been approved before May 27, 2014 in the absence of the Defendants' anticompetitive conspiracy. It appears that Mr. Johnston, like plaintiffs, has been deprived of any information about how Teva reacted internally to what was going on with the FDA's review of its ANDA.

Defendants' one-sided presentation of facts untested by discovery is unfair and threatens the integrity of the trial process. To avoid such prejudice, the district courts have not hesitated to exclude facts identified after the discovery deadline.[15]

III. CONCLUSION

Call it a cat-and-mouse game or sword-and-shield maneuver; it is apparent that defendants may well attempt at trial to backdoor post-May 27, 2014 evidence which has been hidden from plaintiffs to support a foundationless argument that what has actually happened since May 27, 2014 is predictive of what would have happened in the absence of the Defendants' earlier anticompetitive conduct. Plaintiffs spent many months taking discovery of the status of the ANDAs for generic Nexium and preparing to meet Defendants' arguments. This last minute trial by ambush should not be permitted, especially when Defendants refused to supplement the regulatory record when asked by Plaintiffs.

For the foregoing reasons, Defendants should be precluded from introducing argument or evidence about post-May 27, 2014 facts.

Dated: October 17, 2014

[15] *Am. Stock Exch. v. Mopex, Inc.*, 215 F.R.D. 87, 94-95 (S.D.N.Y. 2002) (precluding additional factual claims made after the close of discovery).

/s/ Thomas M. Sobol
Thomas M. Sobol, BBO No. 471770
David S. Nalven, BBO No. 547220
Donna M. Evans, BBO No. 554613
Kristen A. Johnson, BBO No. 667261
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Tel: (617) 482-3700
Fax: (617) 482-3003
tom@hbsslaw.com
davidn@hbsslaw.com
donnae@hbsslaw.com
kristenj@hbsslaw.com

Liaison Counsel and Co-lead Counsel for the Direct Purchaser Class

David F. Sorensen
Daniel Simons
Caitlin G. Coslett
Nicholas Urban
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel: (215) 875-3000
Fax: (215) 875-4604
dsorensen@bm.net
dsimons@bm.net
ccoslett@bm.net

Bruce E. Gerstein
Joseph Opper
Elena Chan
Ephraim R. Gerstein
GARWIN GERSTEIN & FISHER LLP
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055
Fax: (212) 764-6620
bgerstein@garwingerstein.com
jopper@garwingerstein.com
echan@garwingerstein.com
egerstein@garwingerstein.com

Co-lead Counsel for the Direct Purchaser Class

Glen DeValerio (BBO #122010)
BERMAN DeVALERIO
One Liberty Square
Boston, MA 02109
Tel: (617) 542-8300
Fax: (617) 542-1194
gdevalerio@bermandevalerio.com

Todd A. Seaver (BBO #645874)
BERMAN DeVALERIO
One California Street, Suite 900 San Francisco, CA 94111
Tel: (415) 433-3200
Fax: (415) 433-6382
tseaver@bermandevalerio.com

Liaison Counsel for the End-Payor Class

Steve D. Shadowen
HILLIARD & SHADOWEN LLC
39 West Main Street
Mechanicsburg, PA 17055
Tel: (855) 344-3298
steve@hilliardshadowenlaw.com
Anne Fornecker
Daniel Gonzales
HILLIARD & SHADOWEN LLC
919 Congress Ave., Suite 1325
Austin, TX 78701
Tel: (512) 851-8990
anne@hilliardshadowenlaw.com
daniel@hilliardshadowenlaw.com

Kenneth A. Wexler
Bethany R. Turke
Justin N. Boley
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Tel: (312) 346-2222
Fax: (312) 346-0022
kaw@wexlerwallace.com
brt@wexlerwallace.com

jnb@wexlerwallace.com

J. Douglas Richards
George Farah
Sharon K. Robertson
Hiba Hafiz
COHEN MILSTEIN SELLERS & TOLL, PLLC
88 Pine Street, 14th Floor
New York, New York 10005
Tel: (212) 838-7797
Fax: (212) 838-7745
drichards@cohenmilstein.com
srobertson@cohenmilstein.com

Jayne A. Goldstein
POMERANTZ LLP
1792 Bell Tower Lane
Suite 203
Weston, FL 33326
Tel: 954-315-3454
Fax: 954-315-3455
jagoldstein@pomlaw.com

Co-Lead Counsel for the End-Payor Class

Scott E. Perwin
Lauren C. Ravkind
Anna T. Neill
KENNY NACHWALTER P.A.
1100 Miami Center
201 South Biscayne Boulevard
Miami, FL 33131
Tel: 305-373-1000
Fax: 305-372-1861

Counsel for Walgreen Plaintiffs

Barry L. Refsin
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER
One Logan Square, 27th Floor
Philadelphia, PA. 19103
Tel: 215-568-6200

Monica L. Rebuck

HANGLEY ARONCHICK SEGAL PUDLIN
& SCHILLER
4400 Deer Path Road, Suite 200
Harrisburg, PA 17110
Tel.: 717-364-1007

Counsel for Rite Aid Plaintiffs

Bernard D. Marcus
Moira Cain-Mannix
Brian C. Hill
Erin Gibson Allen
MARCUS & SHAPIRA LLP
One Oxford Centre, 35th Floor
Pittsburgh, PA 15219
Tel.: 412-338-3344

Counsel for Giant Eagle, Inc.

CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: October 17, 2014

***/s/* Thomas M. Sobol**
Thomas M. Sobol